

K050478

JUN 15 2005

2.3 Device Names: [807.92(a)(2)]**Proprietary** MEDICON IMF-Orion Screws**Common** Small Bone Screw**Classification** Screw, Fixation, Intraosseous**2.4. Reason for Submission:** [807.81(2)]

New Device

2.5 Predicate Device [807.92(a)(3)]**Manufacturer** Synthes (USA); Paoli.
K010527**Proprietary Name** Synthes (USA) IMF Screws**Catalogue #`s** "IMF Screw Set" GP1852-B
see exhibit 4a**Manufacturer** Walter Lorenz Surgical, Inc.
K983728**Proprietary Name** Lorenz IMF Screws**Catalogue #`s** « 2.0/2.4 MANDIBULAR FRACTURE SYSTEM »
00-2117, p. 4
see exhibit 4b**Manufacturer** KLS-Martin L.P.
K980760**Proprietary Name** KLS-Martin MMF Screw**Catalogue #`s** « FAST-FIX IMF-SYSTEM » 90-848-02
see exhibit 4c**Manufacturer** Howmedica Leibinger, Inc.
K963030**Proprietary Name** Leibinger IMF Screws**Catalogue #`s** « IMF Screw System for Intermaxillary Fixation »
90-01590
see exhibit 4d

2.6 Device Description [807.92(a)(4)]

The MEDICON IMF-Orion Screws are available in different lengths. Thread-lengths within the range of 10.0, 12.0, 14.0 mm and 16.0 mm. The diameter of the shafts is 2.0 mm.

The head shape is in a diameter of 4.0 mm. It is grooved for fastening of wires and rubber bands. For a self-retaining fit to the blade the top is tapered inner hexagonal. The screws are manufactured of Ti6Al-4V according to ASTM F 136-02a.

The MEDICON IMF-Orion Screws provide temporary occlusal and fracture stabilization which can be achieved within a matter of minutes. These screws may be applied prior to or after exposure of the fracture.

The shapes, sizes and materials used are **substantially equivalent** to those of SE devices

2.7 Intended Use: [807.92 (a)(5)]

The Medicon IMF Orion Screws are intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla, mandible or both.

2.8 Environment of Use

The MEDICON IMF-Orion Screws are intended for use in healthcare facilities, including hospitals, medical clinics and surgical centers.

Within these facilities the MEDICON IMF-Orion Screws may be located in areas where sterile surgical/dental instruments are used such as operating rooms for surgery.

2.9 Difference in Design and Technological Characteristics when Compared to SE Devices [807.92(a)(6)]

Material: Like the SE devices, the MEDICON IMF-Orion Screws are manufactured from nonmagnetic, high quality Titanium Alloy (Ti6Al4V) acc. to ASTM F136-02a (DIN ISO 5832-3).

Design: The design is very similar. Both MEDICON and SE devices consist of various sizes regarding length, measurement and fitting of the screw head.

2.10 Discussion of Safety and Effectiveness [807.92(b)]

Clinical results of the MEDICON IMF-Orion Screws made out of Titanium Alloy (Ti6Al4V) and manufactured after ASTM F136-02a have shown their safety and effectiveness:

1. see exhibit 5a: German Literature OP-Journal 2003 "Verwendung von IMF-Schrauben zur mandibulo-maxillären Fixation"
2. see exhibit 5b: German Literature with English abstract p. 361 "Die FAMI-Schraube für die temporäre intermaxillare Fixation"
3. see exhibit 5c: Literature Addenbrooke's NHS "THE INTERMAXILLARY SCREW – A DEDICATED BICORTICAL BONE SCREW FOR TEMPORARY INTERMAXILLARY FIXATION"

2.11 Industry Standards: [807.92 (d)]

MEDICON certifies compliance with required ISO/EN/ASTM and other device-related standards that apply to the manufacture, packaging, labeling, sterilization, and reprocessing of subject devices including the validation of these processes.

Substantially Equivalent**2.12 Information Bearing on the Safety and Effectiveness:
[807.92 (b)(3)]**

The MEDICON IMF-Orion Screws have the same intended use as predicate devices. They are made of identical material according to ASTM F136-02a.

The slight differences in design and size do not adversely affect the safety and effectiveness of this device.

The results of design validation and clinical testing raise no new issues of safety and effectiveness.

2.13 Comparison with predicate devices (table)

	MEDICON	Walter Lorenz	KLS-Martin	Synthes	Howmedica Leibinger
<u>INTENDED USE:</u> The Medicon IMF Orion Screws are intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla, mandible or both.	Yes	Yes	Yes	Yes	Yes
<u>METHODS OF STERILIZATION:</u> Steam Sterilization to SAL of 10^{-6} (For Medicon IMF Orion Screws: 3 times pre-vacuum, 132° C, holding time 4 minutes [full cycle], drying time 10 minutes. Validated according to ISO 14937:2000)	Yes	Yes	Yes	Yes	Yes
<u>MATERIAL:</u>	Ti6Al4V ASTM F136-02a	Ti6Al4V ASTM F136-02a	Ti6Al4V ASTM F136-02a	316-L	Ti6Al4V ASTM F136-02a
<u>DESIGN:</u> Color, Coding: Thread length (mm) Thread function Headshape secures fast and safe gripping Labeling (Packaging shows indications for screw identification) manufactured after ASTM F 136-02a see Exhibit 3	Natural silver 10, 12, 14, 16 self-tapping & selfdrilling Yes Assumed Yes	Gold, Blue (5.0mm) 5, 7, 9, 11 selfdrilling (blue colored 5.0mm) self-tapping (7, 9, 11) Yes Assumed Yes	Gold 9, 11, 13, 15 self-tapping Yes Assumed Yes	Natural silver 8, 12 self-tapping & selfdrilling Yes Assumed Assumed	Gold 8, 14 Self-tapping Yes Assumed Yes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2005

Mr. Joachim Schmid
General Manager
Medicon, E.G.
Gaensaecker 15
Tuttlingen,
GERMANY D-78532

Re: K050478
Trade/Device Name: Medicon IMF Orion Screws
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: June 1, 2005
Received: June 2, 2005

Dear Mr. Schmid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K050478

Device Name: Medicon IMF Orion Screws

Indications for Use: The Medicon IMF Orion Screws are intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla, mandible or both.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050478

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